Plus Kalium Retard 600 mg Tablets

Qualitative and Quantitative Composition:

Active Ingredient: Potassium chloride 600 mg microencapsulated
Inactive Ingredients: Ethylcellulose, talcum, stearic acid, microcrystalline cellulose.

Description

Plus Kalium Retard extended release tablets are oral dosage forms of microencapsulated potassium chloride providing 600 mg of potassium chloride equivalent to 8 mEq of potassium.
The formulation is intended to slow release of potassium chloride, so that a high localized concentration of potassium chloride within the gastrointestinal tract is reduced.
Plus Kalium retard is an electrolyte replenisher. The chemical name of the active ingredient is potassium chloride, and the structural formula is KCl.

Indications and Usage

Plus Kalium Retard is indicated:
For the treatment of patients with hypokalaemia with or without metabolic alkalosis, in digitalis intoxication and in patients with hypokalaemic familial periodic paralysis. If hypokalaemia is the result of diuretic therapy, consideration should be given to the use of a lower dose of diuretic, which may be sufficient without leading to hypokalaemia.
For the prevention of hypokalaemia in patients who would be at particular risk if hypokalaemia were to develop e.g., digitalized patients or patients with significant cardiac arrhythmias, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and certain diarrheal states.
The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern and when low doses of the diuretic are used. Serum potassium should be checked periodically, however, and if hypokalaemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases, and if dose adjustment of the diuretic is ineffective or unwarranted, supplementation with potassium salts may be indicated.

Dosage and Administration

The usual dietary intake of potassium by the average adult is 50 to 100 mEq per day. Potassium depletion sufficient to cause hypokalaemia usually requires the loss of 200 mEq or more of potassium from the total body store.
Dosage must be adjusted to the individual needs of each patient. The dose for the prevention of hypokalaemia is typically 3 x 1 tablet daily or up to 3 x 2 tablets daily for the treatment of potassium depletion. Because of the potential for gastric irritation Plus Kalium retard should be taken after meals. Patients having difficulty swallowing whole tablets may suspend the tablet in a glass of water.

Contradictions

Potassium supplements are contraindicated in patients with hyperkalaemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalaemia may complicate any of the following conditions: chronic renal failure, systemic acidosis, such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of "Overdosage".
All solid oral dosage forms of potassium chloride are contraindicated in any patient in whom there is structural, pathological (e.g. diabetic gastroparesis) or pharmacologic (use of anticholinergic or other agents with anticholinergic properties at sufficient doses to exert anticholinergic effects) cause for arrest or delay in tablet passage through the gastrointestinal tract.

Warnings and Precautions

Hyperkalaemia (see "Overdosage")
In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalaemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalaemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium–Sparing Diuretics
Hypokalaemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone, triamterene, or amiloride) since the simultaneous administration of these agents can produce severe hyperkalaemia.

Interaction with Angiotensin-Converting Enzyme Inhibitors
Angiotensin-converting enzyme (ACE) inhibitors (e.g., captopril, enalapril) will produce some potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ACE inhibitors only with close monitoring.

Metabolic Acidosis
Hypokalaemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

Drug Interactions

Potassium-sparing diuretics, angiotensin-converting enzyme inhibitors (see "Warnings and precaution").

Use in Specific Population

Nursing Mothers
The normal potassium ion content of human milk is about 13 mEq/L. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Paediatric Usage
Safety and effectiveness in paediatric patients have not been established

Geriatric Usage
This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Adverse Reactions

One of the most severe adverse effects is hyperkalaemia (see "Contradictions", "Warnings and precautions" and "Overdosage").
The most common adverse reactions to the oral potassium salts are nausea, vomiting, flatulence, abdominal discomfort, and diarrhoea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals, or reducing the amount taken at one time. Skin rash has been reported rarely with potassium preparations.

Overdosage

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalaemia. It is important to recognize that hyperkalaemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5-8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9-12 mEq/L).

Treatment measures for hyperkalaemia include the following:
Patients should be closely monitored for arrythmias and electrolyte changes.
Elimination of foods and medications containing potassium and of any agents with potassium-sparing properties such as potassium-sparing diuretics, ARBS, ACE inhibitors, NSAIDS, certain nutritional supplements and many others.
Intravenous calcium gluconate, if the patient is at no risk or low risk of developing digitalis toxicity.
Intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10-20 units of crystalline insulin per 1,000 mL.
Correction of acidosis, if present, with intravenous sodium bicarbonate.
Use of exchange resins, haemodialysis, or peritoneal dialysis.
In treating hyperkalaemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.
The extended release feature means that absorption and toxic effects may be delayed for hours. Consider standard measures to remove any unabsorbed drug.

Further Information

Storage
Plus Kalium Retard 600 mg Tablets have to be stored at room temperature (15–25 °C).
Keep all medications away from children and pets. Do not use after expiry date stated on the pack. Properly discard this product when it is expired or no longer needed.

Further information can be obtained from your health care professional.

Product description

What it looks like
Plus Kalium Retard 600 mg Tablet is a white tablet

Date of Information
January 2019

Manufacturer
Amino AG, Wiesenstrasse 21, CH-5412 Gebenstorf, Switzerland

amino ag

THIS MEDICAMENT
Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctors and the pharmacists are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

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